

**K103469 STOCKERT AIR PURGE CONTROL SYSTEM MODEL  
23-45-05**Jan 18, 2011  
55 days to decisionK103469 · Product code: **KRL** · Cardiovascular  
Source: <https://www.510kdatabase.net/k103469/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | Detector, Bubble, Cardiopulmonary Bypass (KRL) |
| Date received         | Nov 24, 2010                                   |
| Decision date         | Jan 18, 2011                                   |
| Days to decision      | 55 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Sorin Group Deutschland GmbH</b>     |
| Location       | North Attleboro, MA, US                 |
| Contact        | ROSINA ROBINSON                         |
| 510(k) history | 20 submissions · 20 cleared · 2006-2017 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103469/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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